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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/755,985 | 01/13/2004 | Brian Blischak | 02-036 US | 2245 |
| 35320 7590 12/11/2008 ST. JUDE MEDICAL NEUROMODULATION 6901 PRESTON ROAD PLANO, TX 75024 | | | | |
| EXAMINER | | | | |
| BHATIA, AARTI | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3763 | | | | |
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| 12/11/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/755,985

Applicant(s)

BLISCHAK, BRIAN

Examiner

Aarti Bhatia

Art Unit

3763

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26, 49 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26, 49 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the fourth Office Action based on the 10/755,985 application filed on 1/13/2004. Claims 18-26, 49, and 52-54, as amended on 9/02/2008, are currently pending and have been considered below.

Response to Arguments

1. Applicant's arguments, see page 6, filed 9/02/2008, with respect to the figures have been fully considered and are persuasive. The objection of the drawings has been withdrawn. The rejection under 35 USC 112 has also been withdrawn.
2. Applicant's arguments with respect to claim 18 have been fully considered but they are not persuasive.
3. Applicant's arguments with respect to claim 49 have been fully considered and are persuasive. The rejection of claims 49 and 51-54 has been withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,139,397 to Tucker et al. in view of U.S. Patent No. 5,700,245 to Sancoff et al.

Tucker discloses a method of operating an implantable infusion drug pump, including delivering to a treatment area a basal flow dosage of the pharmaceutical fluid from a constant flow pump (column 2, lines 16-21), which does not comprise an electrical motor or electrical power supply (column 2, lines 34-35); providing a temporary bolus infusion rate in response to patient manipulation (either manually or magnetically) of an actuator of the implantable infusion drug pump (column 2, lines 22-34), wherein the bolus infusion rate is provided simultaneously to the basal infusion rate.

Tucker fails to teach the working fluid for the bolus infusion.

Sancoff teaches a method comprising: wherein the providing a temporary bolus infusion rate comprises manually applying pressure (figure 2) to a working fluid contained in an actuator (10) associated with an implantable pharmaceutical fluid delivery device (5), wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir (27) and a second fluid reservoir (17), thereby causing a flow of the working fluid into the first fluid reservoir (figure 2 with respect to figure 1); delivering to the treatment area a first dosage of pharmaceutical fluid (20) from the

second fluid reservoir by transferring pressure from the working fluid in the first reservoir to the pharmaceutical fluid in the second reservoir (abstract), wherein the working fluid (gas) and the pharmaceutical fluid (20) are different fluids; comprising drawing working fluid from the first fluid reservoir into the actuator, causes a filling of the second fluid reservoir (17) with pharmaceutical fluid (20), wherein the delivering to the treatment area a first dosage comprises drawing the working fluid (gas) into the actuator from the first fluid reservoir thereby causing pharmaceutical fluid to be expelled from the second fluid reservoir wherein the actuator is selected from the group consisting of a compressible button and a bulb (60), driving infusate from the main reservoir is performed by an elastomeric diaphragm (25); wherein the secondary reservoir is adapted to hold a maximum fluid volume that is greater than a maximum fluid volume of the working fluid reservoir (see figure 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Tucker with the bolus delivery method of Sancioff, since the working fluid of Sancioff provides for a very controlled delivery rate. Further it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate piston and cylinder devices into the fluid reservoirs as these are well-known features in the art (see for example U.S. Patent No. 6,736,795 to Michel).

Allowable Subject Matter

7. Claims 49 and 52-54 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763